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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,354	02/27/2004	Pier Francesco Cirillo	9/276	9059

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EXAMINER

DESAI, RITA J

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/789,354

Applicant(s)

CIRILLO ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-18 is/are rejected.
- 7) ☒ Claim(s) 1-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1625

## **DETAILED ACTION**

### ***Election/Restrictions***

The examiner has made another group IV drawn to compounds and compositions wherein R's have a hetero cyclic group. A single disclosed species is required. May be subject to further restriction.

Applicants have elected group I of the restriction claims 1-14 drawn to compounds and compositions wherein Ar1 is as given in claim 3. all the R values should not include a hetero ring nor should it form a hetero ring, J is an alkyl, W is a CH, Y is N and Q is a >CRpRv, { Applicants should note that when they amend the claims all R's which includes Rp and Rv and also the substitutions for e.g. Rb also should not contain any hetero cyclic groups nor should adjacent R's form a hetero cyclic ring}. Claim 13 should be amended by deleting all the species that would not fall within the scope of the elected group.

Applicants preserve their right to file a divisional on the canceled non-elected claims in due course without prejudice.

The Restriction is now made FINAL.

### ***Inventorship***

In view of the papers filed 9/24/04, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a)1. The inventorship of this application has been changed by adding

Roland A. Aungst

Art Unit: 1625

The petition has been granted and the above named inventor has been added.

The compound claims were found to be allowable and hence the method of treating and a process of making limited to the scope of the allowable claims is being rejoined.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inflammation, does not reasonably provide enablement for all the various oncological diseases and all the other diseases as given in claim 16 and 17. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Art Unit: 1625

Applicants claim is to a large genus and there is very little predictability in the art that drugs would have an umbrella efficacy of treating any and all the various diseases as claimed.

Caffeine and theophylline differ in a methyl substituent and yet their properties are very different. One of them is a broncho dilator.

There is very little direction given in the specification that all these diseases would be treatable by the compound.

Applicants can overcome this by limiting the claim to the enable disease.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a process however the process does not clearly indicate the steps and conditions for making them.

### ***Conclusion***

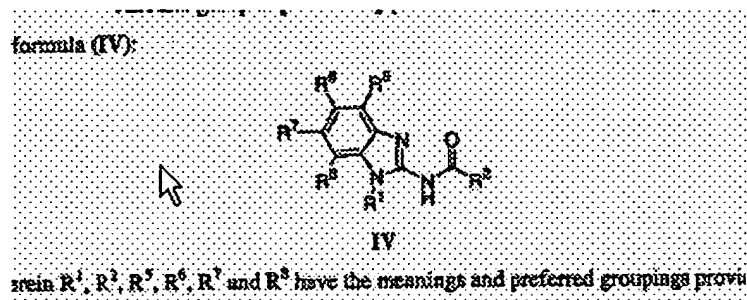
Claims 1-14 limited to the elected scope are allowable however the claims 15-18 are rejected.

Closest Art is WO 03/030902 Tularik et al with a US provisional 60/327,818 filed 9/10/2001.

Applicants claims are drawn to compounds of the formula

The prior art teaches a genus which encompasses the claimed compounds. See pages 20-22 formula IV, R2 is a phenyl.

Art Unit: 1625



The difference is that the linkage between the benzimidazole and the R<sub>2</sub> is NHC=O, instead of the C=ONH linkage and also R<sub>5</sub> and R<sub>6</sub> are OR' wherein R' is a hetero aryl amongst many other variables.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.D.  
May 27, 2005

*Rita J. Desai*  
5/31/05

Rita J. Desai  
Primary Examiner  
Art Unit 1625